

Appl. No. : **09/776,232**
Filed : **February 02, 2001**

AMENDMENTS TO THE CLAIMS

1-37. (Cancelled)

38. (Amended) A method of inducing a CTL response in a mammal, which method comprises:

delivering a liquid comprising ~~a cell-free~~ an antigen directly to a lymph node or lymph vessel of the mammal at a level sufficient to induce a CTL response in the mammal; and

maintaining the antigen in the mammal's lymphatic system over time sufficient to induce the CTL response.

39. (Previously added) The method of Claim 38, wherein the antigen is delivered directly to a lymph node.

40. (Previously added) The method of Claim 38, wherein the antigen comprises a protein or peptide.

41. (Previously added) The method of Claim 38, wherein the antigen is delivered in a single bolus.

42. (Previously added) The method of Claim 38, wherein the antigen comprises a microorganism.

43. (Previously added) The method of Claim 38, wherein the antigen is delivered in the form of a nucleic acid encoding the antigen.

44. (Previously added) The method of Claim 43, wherein said nucleic acid is plasmid DNA in a formulation comprising about 1-10% ethyl alcohol, 0-1% benzyl alcohol, 0.25-0.5mM EDTA and a citrate-phosphate buffer of pH 7.4-7.8, comprising about 3-50mM citrate and about 90-200mM phosphate.

45. (Amended) A method of inducing a CTL response in a mammal, which method comprises:

delivering a liquid comprising ~~a cell-free~~ an antigen in a continuous, repeated, or sustained manner directly to a lymph node or lymph vessel of the mammal at a level sufficient to induce a CTL response in the mammal; and

maintaining the antigen in the mammal's lymphatic system over time sufficient to induce the CTL response.

Appl. No. : **09/776,232**
Filed : **February 02, 2001**

46. (Previously added) The method of Claim 45, wherein induction of cytotoxic T lymphocytes is obtainable independent of immunopotentiator.

47. (Previously added) The method of Claim 46, wherein the antigen is delivered with a cytokine.

48. (Previously added) The method of Claim 46, wherein the antigen is delivered in the form of a nucleic acid encoding the antigen.

49. (Previously added) The method of Claim 45, wherein the antigen is provided as a component of a microorganism cell, and wherein said microorganism cell comprises a recombinant nucleic acid encoding or promoting expression of said antigen.

50. (Previously added) The method of Claim 45, wherein the CTL response comprises an immunological CTL response.

51. (Previously added) The method of Claim 45, further comprising obtaining a sustained CTL response in the mammal and detecting a CTL response in the mammal.

52-59. (Cancelled)

60. (Previously Amended) The method of Claim 38, wherein said delivering step further comprises delivering said liquid directly to the lymph node or lymph vessel of the mammal from a device external to the mammal.

61. (Previously Amended) The method of Claim 45, wherein said delivering step further comprises delivering said liquid directly to the lymph node or lymph vessel of the mammal from a device external to the mammal.

62. (Previously Added) The method of Claim 38, wherein the antigen is delivered continuously over a period of time.

63. (New) The method of Claim 38, wherein the antigen is selected from the group consisting of a peptide, a polypeptide, a polyepitope amino acid sequence, and a protein.

64. (New) The method of Claim 38, wherein the antigen is a component or lysate of a microorganism or mammalian cell.

65. (New) The method of Claim 38, wherein the antigen is provided as a vector carrying and/or conferring expression of the antigen.

66. (New) The method of Claim 65, wherein the vector is selected from the group consisting of a bacterium, a virus, a protozoan, and a professional antigen-presenting cell.

67. (New) The method of Claim 66, wherein the vector is a dendritic cell.

Appl. No. : **09/776,232**
Filed : **February 02, 2001**

68. (New) The method of Claim 45, wherein the antigen is selected from the group consisting of a peptide, a polypeptide, a polyepitope amino acid sequence, and a protein.

69. (New) The method of Claim 45, wherein the antigen is a component or lysate of a microorganism or mammalian cell.

70. (New) The method of Claim 45, wherein the antigen is provided as a vector carrying and/or conferring expression of the antigen.

71. (New) The method of Claim 70, wherein the vector is selected from the group consisting of a bacterium, a virus, a protozoan, and a professional antigen-presenting cell.

72. (New) The method of Claim 71, wherein the vector is a dendritic cell.

73. (New) The method of Claim 45, wherein the antigen comprises a microorganism.

Appl. No. : **09/776,232**
Filed : **February 02, 2001**

SUMMARY OF INTERVIEW

The follow is a summary of an interview held at the U.S.P.T.O. on Tuesday, January 27, 2004, with Examiners Huynh and Gabel and Applicants' representatives, Dale Hunt, David Diamond, Thomas Kundig, and Marc Morley, and a telephonic interview held on Wednesday, February 4, 2004, with Supervisor, Christina Chan and Applicants' representative, Dale Hunt. Applicants again thank Examiners Huynh, Gabel, and Chan for their time and discussion during the interviews.

Exhibits and/or Demonstrations

No exhibits or Demonstrations were presented during the interview.

Identification of Claims Discussed

All of the pending claims were discussed.

Identification of Prior Art Discussed

All of the art cited in the pending Office Action was discussed, including Issekutz, *Clin. Exp. Immunol.* 56:515-23 (1984) (Issekutz); Grohmann et al., *J. Immunol. Methods* 137:9-16 (1991) (Grohmann); and Klavinskis et al., *J. Immunol.* 157:2521-27 (1996) (Klavinskis).

Proposed Amendments

No specific proposed amendments were agreed upon. Applicants agreed to consider possible amendments, and to present any such amended claims in the instant written response.

Principal Arguments and Other Matters

Examiners Huynh and Gabel and Applicants' representatives reviewed and discussed the outstanding Office Action, specifically, the 35 U.S.C. § 112 written description and enablement rejections, the art rejections under 35 U.S.C. §§ 102(b) and 103(a), and the patentability of the claims.

Supervisor Christina Chan and Applicants' representative recapped these issues during the subsequent telephonic interview.

Results of Interview

No agreements were reached, except that Examiner Huynh will reconsider the references Issekutz et al., Grohmann et al., and Klavinskis et al., and the art rejections under

Appl. No. : **09/776,232**
Filed : **February 02, 2001**

35 U.S.C. §§ 102(b) and 103(a). The Examiner will discuss the 35 U.S.C. § 112 enablement and written description rejections with Supervisor, Christina Chan.